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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,650	06/27/2003	Dennis D. Garvin	41097.001	2638

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EXAMINER
POUS, NATALIE R

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 08/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/607,650	GARVIN, DENNIS D.	
	Examiner	Art Unit	
	Natalie Pous	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-9,13 and 16-19* is/are pending in the application.

4a) Of the above claim(s) *18 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-9,13,16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *18 and 19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/1/04,10/15/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Regarding the abstract

Examiner acknowledges the submission of amended abstract. Objection to the abstract is withdrawn

Regarding the 35 USC 102 and 103 rejections

Applicant's arguments with respect to claims 1-16 have been considered but are moot in view of the new ground(s) of rejection.

In response to applicant's argument that the Sutherland et al. reference is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Sutherland is pertinent to the particular problem with which the applicant was concerned, that being to securely hold separated tissue in apposition so as the tissue heals or forms a closure.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a

reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Election/Restrictions

Newly submitted claims 18-19 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 6-9, 13, 16 and 17, drawn to apparatus, classified in class 606, subclass 218.

II. Claims 18-19, drawn to process of using, classified in class 218, subclass 898.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case (2) the product as claimed may be used on portions of the body other than the skin, for instance the product as claimed may be used to close a wound in internal tissue, such as muscle.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 18-19 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6-9, 13, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brotz (US 5584859) in view of Hasson (US 3926193).

Brotz teaches a wound closure device for connecting tissue (10) comprising at least one pair of flexible straps wherein:

- the first flexible strap (14) has a proximal end (46) and a distal end, and a ventral surface and a dorsal surface. It is noted that any strap inherently comprises a proximal and distal end, and a ventral and dorsal surface
- the second flexible strap (15) has a proximal end (48) and a distal end, and a ventral surface and a dorsal surface

- wherein the proximal end terminates in a connector (12) designed and configured to adjustably connect (Column 4, proximate lines 60-68, Column 5, proximate lines 1-16) to the proximal end of the first strap (46)
- wherein the first strap and the second strap have at least one barb (16) on the ventral surface for engaging the tissue
- whereby the straps form a wound closure (Column 1, proximate lines 10-15).
- wherein the first strap (14) and the second strap (15) are placed in the fascia (30, 32) of the wound.
- wherein the device is made of resorbable material (Column 2, proximate lines 32-35).
- wherein a plurality of barbs is present on the ventral surface (Column 2, proximate lines 40-47) of the first and second straps (Column 2, proximate lines 10-14).
- wherein the first and second straps are placed in the wound by the use of a trochar (Column 2, proximate lines 26-32). It is noted that in the present case, the device itself is a trochar.

Brotz fails to teach

- Wherein the straps are isolated
- The first strap has a proximal end with a male connector
- The second strap has a proximal end with a female connector

- Wherein the female connector is configured to adjustably connect to the male connector of the first strap
- Wherein the female end comprises a buckle
- Wherein the male end of the first strap includes a ratcheted surface to accommodate the buckle of the female end

Hasson teaches a surgical closure device comprising isolated straps (35, 37), the first strap has a proximal end with a ratcheted male connector (22), the second strap has a proximal end with a female connector buckle (32), wherein the female connector is configured to adjustably connect to the male connector of the first strap (Column 1, proximate lines 48-54) in order to provide a wound closure device that may be adjusted and readjusted as often as necessary and may be selectively locked as desired with a variable degree of closing pressure or firmness along its length. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the wound closure device of Brotz as taught by Hasson in order to provide a wound closure device that may be adjusted and readjusted as often as necessary and may be selectively locked as desired with a variable degree of closing pressure or firmness along its length.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
7/24/06

(JACKIE) TAN-UYEN HO
PRIMARY EXAMINER

8/3/06